UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
GREENEVILLE

UNITED STATES OF AMERICA	)	
	)	
v.	)	2:12-CR- 116
	)	
WILLIAM RALPH KINCAID	)	

PLEA AGREEMENT

The United States of America, by the United States Attorney for the Eastern District of Tennessee, and the defendant, William Ralph Kincaid, and the defendant's attorney, Mark D. Slagle, have agreed upon the following:

1. The defendant will waive indictment and arraignment and plead guilty to an Information charging the defendant with the following offense:

a) Count One, which charges the defendant with receiving in interstate commerce a misbranded drug with intent to defraud or mislead in violation of 21 U.S.C. § 331(c). The punishment for this offense is as follows: a term of imprisonment of not more than three years (21 U.S.C.§ 333(a)(2)); a fine of not more than $250,000 (18 U.S.C. § 3571(b)(3)); a term of supervised release of not more than one year (18 U.S.C. § 3583(b)(3)); a term of probation of not less than one nor more than five years (18 U.S.C. § 3561(c)(1)); and a special assessment of $100 (18 U.S.C.§ 3013(a)(2)(A)).

2. The United States also agrees not to further prosecute the defendant in the Eastern District of Tennessee for any other non-tax criminal offenses committed by the defendant related to the charges contained in this information.

3. The defendant has read the information, discussed the charges and possible defenses with defense counsel, and understands the crime charged. The defendant is pleading guilty because

the defendant is in fact guilty. In order to be guilty, the defendant agrees that each of the following elements of the crime must be proved beyond a reasonable doubt:

(1) the defendant received prescription drugs in interstate commerce for delivery for pay or otherwise;

(2) the prescription drugs were misbranded; and

(3) the defendant acted with intent to defraud or mislead.

4. In support of the defendant's guilty plea, the defendant agrees and stipulates to the following facts, which satisfy the offense elements. These are the facts submitted for purposes of the defendant's guilty plea. They do not necessarily constitute all of the facts in the case. Other facts may be relevant to sentencing. Both the defendant and the United States retain the right to present additional facts to the Court to ensure a fair and appropriate sentence in this case.

> At all times relevant to this case, East Tennessee Hematology-Oncology Associates, P.C., doing business as McLeod Cancer and Blood Center, Johnson City, Tennessee (hereinafter "McLeod Cancer"), was a professional corporation providing care and treatment for patients with cancer and blood diseases. William R. Kincaid, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was president, majority owner, and managing partner of McLeod Cancer. Millard Ray Lamb, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was a part owner of and practiced medicine in McLeod Cancer. Charles Olugbenga Famoyin, M.D., a medical doctor licensed to practice medicine in the State of Tennessee, was a part owner and practiced medicine in McLeod Cancer. Michael Dean Combs was employed as business manager for McLeod Cancer.
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> As part of the treatment of patients for cancer and other diseases, McLeod Cancer purchased large amounts of assorted prescription drugs, to include chemotherapy drugs, which were prescribed by Drs. Kincaid, Lamb, and Famoyin and were administered and dispensed through McLeod Cancer. Reimbursement for the drugs and their administration was sought from the Medicare and Medicaid (TennCare) programs, as well as other health benefits programs.
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> Quality Specialty Products (QSP) was a business in Winnipeg, Canada, offering for sale to physicians and other health care providers in the United States drugs which had been obtained from foreign sources and which had not been

approved by the U.S. Food and Drug Administration for distribution or use in the United States. QSP later did business jointly with a business called Montana Healthcare Solutions, Inc.(MHS), Belgrade, Montana.

The U.S. Food and Drug Administration

The United States Food and Drug Administration ("FDA") was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumers to use them in a safe manner and that drugs were listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. 21 U.S.C. §§ 352(f), 352(o) and 360(c).

Under the FDCA, anyone manufacturing, preparing, compounding, or processing prescription drugs for sale and use in the United States must annually register with the FDA as a drug establishment, and provide a list to FDA of the drugs which are being manufactured for commercial distribution. 21 U.S.C. §§ 360(a)(1), 360(b), 360(i) and 360(j). The FDCA's registration requirement applies to both businesses located within the United States and drug establishments outside of the United States that import their drugs into the United States. 21 U.S.C. §§ 360(b), 360(i). Any drug establishment, located within or outside of the United States, may be inspected by FDA or officials of foreign governments that act cooperatively with FDA. 21 U.S.C. §§ 360(h), 360(i)(3).

Prescription Drugs

Under the FDCA, drugs included: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, articles intended to affect the structure or any function of the body of man, and "biological products" applicable to the prevention, treatment, or cure of a disease or condition of human beings. 21 U.S.C. § 321(g)(1)(B) and (c); 42 U.S.C.§ 262(I).

Under the FDCA, a drug was deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355.

The drugs listed below, using the names under which the drugs are marketed in the United States, are used primarily to treat individuals with cancer, and are often "infused" into cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very important for patients. All of these drugs were "prescription drugs" pursuant to 21 U.S.C. § 353(b)(l) because of their toxicity or other potentiality for harmful effect, and could lawfully be dispensed only upon the prescription of a practitioner licensed by law to administer such drugs:

ABRAXANE® (Paclitaxel Injection)
ALIMTA® (Pemetrexed Injection)
AVASTIN® (Bevacizumab Injection)
ELOXATIN® (Oxaliplatin Injection)
GEMZAR® (Gemcitabine Hydrochloride)
HERCEPTIN® (Trastuzumab Injection)
RITUXAN® (Rituximab Injection)
TAXOTERE® (Docetaxel Injection)
ZOMETA® (Zoledronic Acid Injection)

Misbranding

Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is misbranded under the FDCA unless the labeling bore adequate directions for use. 21 U.S.C. § 352(f). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R.§ 201.5. All words, statements, and other information required to appear on drug labeling by the FDCA must be in the English language, unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. § 201.15(c)(l). A drug is also "misbranded" if it was manufactured, prepared, propagated, compounded, and processed in any establishment in any state not duly registered with FDA. 21 U.S.C. § 352(o). Finally, any drug is misbranded if it came from a domestic or foreign drug establishment and that drug was not annually listed with the FDA by the establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment. 21 U.S.C. §§ 352(o), 360(j).

Reimbursement for Cancer Drugs

Medicare Part B currently covers a limited number of outpatient prescription drugs and biologicals (collectively referred to as drugs). Those that are covered include injectable drugs administered by a physician; certain self-administered drugs, such as oral anti-cancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 established a new methodology for Medicare Part B reimbursement of most covered drugs. Effective January 1, 2005, reimbursement to physician practices for drugs is generally set at 106 percent of the average sales price (ASP). The ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that quarter. The ASP is net of any price concessions and excludes certain sales, including those at a nominal charge.

The Medicare program, along with other government health benefits programs (to include TennCare, Tennessee's Medicaid program, and the Federal Employees Health Benefits Plan) provide reimbursement only for FDA-approved drugs, and a physician or health care provider submitting a claim for reimbursement for a covered drug represents that the drug administered or dispensed was an FDA-approved drug.

The U.S. Department of Health and Human Services Office of Inspector General reported to Congress in 2005 that physician practices in the specialties of hematology, hematology/oncology, and medical oncology could generally purchase drugs from FDA-approved sources for the treatment of cancer patients at less than the established reimbursement rates. Further, FDA reported that there were no shortages within the United States of the above-listed drugs during the period 2007-2012.

Misbranded Drugs At McLeod Cancer and Blood Center

In September 2007, Dr. Lamb received a fax mailer from QSP which offered for sale certain prescription drugs, including chemotherapy drugs, along with price information for the drugs, the prices being less than what McLeod Cancer had been paying to purchase the drugs from FDA-approved sources in the United States. A decision was made by Drs. Kincaid, Lamb, and Famoyin to have Combs begin ordering drugs from QSP, and QSP began shipping misbranded unapproved drugs to McLeod Cancer, to include the drugs listed above, where the drugs were administered to patients and claims for reimbursement were submitted to Medicare, TennCare, and other health benefits programs. As business manager, Combs participated in the ordering of drugs from QSP.

The drugs provided by QSP to McLeod Cancer were drugs from foreign sources that were not inspected and approved by the FDA, to include drugs which had been distributed in Turkey, India, the European Union, and elsewhere.

In late 2007 and early 2008, nurses at McLeod Cancer observed that packaging for chemotherapy drugs which were being obtained by McLeod Cancer from QSP bore labeling in foreign languages, establishing that the drugs were not approved for use in the United States. After the nurses raised their concerns with Drs. Kincaid,

Lamb and Famoyin and with Combs, the decision was made to stop ordering drugs from QSP.

In approximately August 2009, Dr. Kincaid and Combs were re-contacted by QSP. A meeting was held with the QSP representative, Dr. Kincaid, Combs and a fourth person at a Johnson City, Tennessee restaurant where Dr. Kincaid decided McLeod Cancer would resume purchasing misbranded unapproved drugs from QSP. Combs was responsible for placing the orders with QSP.

To prevent the nurses from learning that McLeod Cancer was again purchasing unapproved foreign drugs, Dr, Kincaid directed Combs to have the drugs shipped to a storage business in Johnson City which Dr. Kincaid owned in part. The drugs, after having been received at the storage business, were transported by Combs and others to Combs' office at McLeod Cancer and then placed by a pharmacy technician into the clinic's drug storage and control system where the misbranded drugs were mingled with FDA-approved drugs from legitimate sources. FDA-approved drugs obtained from legitimate U.S. drug manufacturers and distributors were still shipped directly to McLeod Cancer and not to the storage business.

McLeod Cancer obtained misbranded unapproved drugs, to include the drugs listed above, from QSP and MHS from approximately September 2007 to early 2008 and from August 2009 to February 2012, purchasing over $2 million in misbranded unapproved drugs, providing those drugs to their patients, and billing Medicare, TennCare, and other government health benefits programs approximately $2.5 million for the unapproved drugs.

The labeling for the prescription drugs purchased by McLeod Cancer from QSP and MHS was different than the versions of these drugs that had been approved for sale in the United States by the FDA. For example, some of the labeling for some of the drugs from QSP/MHS was in foreign languages. Other drugs' labeling did not provide dosage information, or express the potency of the drugs in a standard format. 21 C.F.R. §§ 201.56, 610.6l(n), (r). None of the drugs purchased by McLeod Cancer came from registered drug establishments, were annually listed as drugs being produced at registered drug establishments, or contained National Drug Codes.

Rituximab is used alone or with other medications to treat certain types of non-Hodgkin's lymphoma. All of the prescription drug Rituximab (marketed in the United States as Rituxan®) ordered by McLeod Cancer and provided by QSP/MHS was labeled "MabThera®." The labeling for the Rituximab/MabThera® obtained by McLeod Cancer says that the drug came from an unregistered drug establishment located in Switzerland that did not provide FDA with an annual list of any drugs manufactured there, and was distributed after manufacturing by another company located in New Delhi, India. By contrast, the FDA-approved version of Rituximab that is made for legal use in the United States is labeled "Rituxan®." Rituxan® is manufactured in a registered drug establishment in Vacaville, California. This drug

establishment annually lists the drug Rituxan® with the FDA as a drug that it is manufacturing at that facility. The FDA can also routinely inspect that California-based drug establishment.

Further, Rituximab (to include both Rituxan® and MabThera®) is a drug which must be "cold chained," that is, a prescription drug that requires a uniform cold temperature during shipment. The U.S. labeling for this drug requires storage of the drug in a refrigerator at 2° to 8°C (36° to 46°F), and cautions that the drug should not be frozen or shaken. Failure to properly ship and store the drug can render it ineffective.

Records reflect that on or about November 7, 2011, QSP shipped to the storage business in Johnson City, Tennessee the drug Rituximab, labeled as "MabThera®," in both 100mg/10ml and 500 mg/50 ml dosages/strengths, along with other drugs. The MabThera® had been manufactured by F. Hoffman-LaRoche Ltd. in Switzerland and had been distributed to Taksal Pharma Pvt. Ltd. in New Delhi, India. The drugs had been transported from India to the United Kingdom; from there, the drugs were sent to a re-shipping service used by QSP in Chicago, Illinois, who sent the drugs on to Johnson City. The drug's labeling failed to bear adequate directions for use in that part of the drug's labeling was in the Hindi language; further, the drug came from a foreign drug establishment and that drug was not annually listed with the FDA by that establishment as one of the drugs which was being manufactured for commercial distribution in the United States at that drug establishment. The drugs were received and stored at the storage business and were transported as needed to Combs' office at McLeod Cancer. A pharmacy technician then obtained the drugs and placed them into McLeod Cancer's drug storage and control system, from which the drugs were administered by infusion to chemotherapy patients at the clinic's two locations in Johnson City. Claims for reimbursement for the Rituximab/MabThera® so administered were then made to Medicare, TennCare, and other health benefits programs.

5. The defendant understands that by pleading guilty the defendant is giving up several rights, including:

a) the right to be indicted by a grand jury for the offense;

b) the right to plead not guilty;

c) the right to a speedy and public trial by jury;

d) the right to assistance of counsel at trial;

e) the right to be presumed innocent and to have the burden of proof placed on the United States to prove the defendant guilty beyond a reasonable doubt;

f) the right to confront and cross-examine witnesses against the defendant;

g) the right to testify on one's own behalf, to present evidence in opposition to the charges and to compel the attendance of witnesses; and

h) the right not to testify and to have that choice not used against the defendant.

6. The parties agree that the appropriate disposition of this case would be the following as to each count:

a) The Court may impose any lawful term of imprisonment, any lawful fine, and any lawful term of supervised release up to the statutory maximums;

b) The Court will impose special assessment fees as required by law; and

c) The Court may order forfeiture as applicable and restitution as appropriate.

No promises have been made by any representative of the United States to the defendant as to what the sentence will be in this case. Any estimates or predictions made to the defendant by defense counsel or any other person regarding any potential sentence in this case are not binding on the Court, and may not be used as a basis to rescind this plea agreement or withdraw the defendant's guilty plea. The defendant understands that the sentence in this case will be determined by the Court after it receives the presentence report from the United States Probation Office and any information presented by the parties. The defendant acknowledges that the sentencing determination will be based upon the entire scope of the defendant's criminal conduct, the defendant's criminal history, and pursuant to other factors and guidelines as set forth in the Sentencing Guidelines and the factors set forth in 18 U.S.C. § 3553.

7. Given the defendant's agreement to plead guilty, the United States will not oppose a two-level reduction for acceptance of responsibility under the provisions of Section 3E1.1(a) of the Sentencing Guidelines. Further, if the defendant's offense level is 16 or greater, and the defendant is awarded the two-level reduction pursuant to Section 3E1.1(a), the United States agrees to move, at

or before the time of sentencing, the Court to decrease the offense level by one additional level pursuant to Section 3E1.1(b) of the Sentencing Guidelines. Should the defendant engage in any conduct or make any statements that are inconsistent with accepting responsibility for the defendant's offense(s), including violations of conditions of release or the commission of additional offenses prior to sentencing, the United States will be free not to make such motion or to withdraw such motion if already made, and will be free to recommend to the Court that the defendant not receive any offense level reduction for acceptance of responsibility under Section 3E1.1 of the Sentencing Guidelines.

8. The defendant agrees to pay the special assessment in this case prior to sentencing.

12. Financial Obligations. The defendant agrees to pay all fines and restitution imposed by the Court to the Clerk of Court. The defendant also agrees that the full fine and/or restitution amounts shall be considered due and payable immediately. If the defendant cannot pay the full amount immediately and is placed in custody or under the supervision of the Probation Office at any time, the defendant agrees that the Bureau of Prisons and the Probation Office will have the authority to establish payment schedules to ensure payment of the fine and/or restitution. The defendant further agrees to cooperate fully in efforts to collect any financial obligation imposed by the Court by set-off of federal payments, execution on non-exempt property, and any other means the United States deems appropriate. The defendant and counsel also agree that the defendant may be contacted post-judgment regarding the collection of any financial obligation imposed by the Court without notifying the defendant's counsel and outside the presence of the defendant's counsel. In order to facilitate the collection of financial obligations to be imposed with this prosecution, the defendant agrees to disclose fully all assets in which the defendant has any interest or over which the defendant exercises control, directly or indirectly, including those held by a spouse, nominee, or

other third party. In furtherance of this agreement, the defendant additionally agrees to the following specific terms and conditions:

a) If so requested by the United States, the defendant will promptly submit a completed financial statement to the U.S. Attorney's Office, in a form it provides and as it directs. The defendant promises that such financial statement and disclosures will be complete, accurate, and truthful.

b) The defendant expressly authorizes the U.S. Attorney's Office to obtain a credit report on the defendant in order to evaluate the defendant's ability to satisfy any financial obligation imposed by the Court.

c) If so requested by the United States, the defendant will promptly execute authorizations on forms provided by the U.S. Attorney's office to permit the U.S. Attorney's Office to obtain financial and tax records of the defendant.

13. (a) In consideration of the concessions made by the United States in this agreement and as a further demonstration of the defendant's acceptance of responsibility for the offense committed, the defendant agrees not to file a direct appeal of the defendant's conviction or sentence except the defendant retains the right to appeal a sentence imposed above the sentencing guideline range determined by the district court.

(b) In addition, the defendant knowingly and voluntarily waives the right to file any motions or pleadings pursuant to 28 U.S.C. § 2255 or to collaterally attack the defendant's conviction and/or resulting sentence. The parties agree that the defendant retains the right to raise, by way of collateral review under § 2255, claims of ineffective assistance of counsel or prosecutorial misconduct not known to the defendant by the time of the entry of judgment.

14. This agreement becomes effective once it is signed by the parties and is not contingent on the defendant's entry of a guilty plea. If the United States violates the terms of this agreement, the defendant will have the right to withdraw from this agreement. If the defendant violates the terms of this agreement in any way (including but not limited to failing to enter guilty plea as agreed

herein, moving to withdraw guilty plea after entry, or by violating any court order or any local, state or federal law pending the resolution of this case), then the United States will have the right to void any or all parts of the agreement and may also enforce whatever parts of the agreement it chooses. In addition, the United States may prosecute the defendant for any and all federal crimes that the defendant committed related to this case, including any charges that were dismissed and any other charges which the United States agreed not to pursue. The defendant expressly waives any statute of limitations defense and any constitutional or statutory speedy trial or double jeopardy defense to such a prosecution. The defendant also understands that a violation of this plea agreement by the defendant does not entitle the defendant to withdraw the defendant's guilty plea in this case.

15. This plea agreement constitutes the full and complete agreement and understanding between the parties concerning the defendant's guilty plea to the above-referenced charge and there are no other agreements, promises, undertakings, or understandings between the defendant and the United States. The parties understand and agree that the terms of this plea agreement can be modified only in writing signed by all of the parties and that any and all other promises, representations, and statements whether made before, contemporaneous with, or after this agreement, are null and void.

WILLIAM C. KILLIAN
UNITED STATES ATTORNEY

11/15/2012
Date

By: _____
M. Neil Smith
Assistant United States Attorney

11/14/12
Date

_____
William Ralph Kincaid
Defendant

11/14/12
Date

_____
Mark D. Slagle
Attorney for the Defendant

Nov. 14, 2012
Date

_____
Guy W. Blackwell
Attorney for the Defendant